

1091733
AUG 28 2009**APPENDIX A: 510(K) SUMMARY**

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| Submitter | MAQUET Cardiovascular LLC |
| Submitter's Address | 40 Barbour Pond Drive Wayne, NJ 07470 |
| Telephone | (408) 635-3987 |
| Fax | (408) 635-3907 |
| Contact Person | Artie Kaushik |
| Date Prepared | June 10, 2009 |
| Device Trade Name | VASOVIEW 6 PRO Endoscopic Vessel Harvesting System |
| Device Common Name | Electrosurgical cutting and coagulation device and accessories |
| Device Classification Name | Electrosurgical cutting and coagulation device and accessories |
| Device Classification | Class II |
| Summary of substantial equivalence | The design, materials, method of delivery, and intended use features of the VASOVIEW 6 PRO Endoscopic Vessel Harvesting System are substantially equivalent with regard to those features in the predicate device: the VV6 (K041981, August 20, 2004) and VASOSHIELD Pressure Controlling Syringe (K082725, December 17, 2008) |
| Device description | The VASOVIEW 6 PRO Endoscopic Vessel Harvesting System consists of the VASOVIEW 6 PRO Harvesting Cannula which is designed for use in conjunction with the 7mm Endoscope. The Harvesting Cannula has four lumens which house the Endoscope, C-Ring wire, endoscope washer tube and Bipolar BiSector for ligation and division of vessel branched. The system includes the following accessories- (1) The 7mm Extended Length Endoscope and Dissection Tip for blunt dissection of tissue and isolation of structures in the cavity. (2) Shortport Blunt Tip Trocar (BTT) to provide a port for insertion of endoscopic instruments into an incision site. (3) VASOSHIELD Pressure Controlling Syringe is a fully assembled 60 mL syringe with a pressure relief valve that is controlled by a pressure setting ring. |

Indications for Use

The VASOVIEW 6 PRO System is indicated for use in minimally invasive surgery allowing access for vessel harvesting, and is primarily indicated for patients undergoing endoscopic surgery for arterial bypass. It is indicated for cutting tissue and controlling bleeding through coagulation, and for patients requiring blunt dissection of tissue including dissection of blood vessels, dissection of blood vessels of the extremities, dissection of ducts and other structures in the extraperitoneal or subcutaneous extremity and thoracic space. Extremity procedures include tissue dissection/vessel harvesting along the saphenous vein for use in coronary artery bypass grafting and peripheral artery bypass or radial artery for use in coronary artery bypass grafting. Thoracoscopic procedures include exposure and dissection of structures external to the parietal pleura, including nerves, blood vessels and other tissues of the chest wall.

The VASOSHIELD Pressure Controlling Syringe is indicated for controlling pressure during the preparation and irrigation of blood vessels prior to use as a bypass graft.

Technological characteristics

The VASOVIEW 6 PRO Endoscopic Vessel Harvesting System incorporates the same fundamental scientific technology as the predicate devices.

Performance data

The results of the verification testing demonstrate that the VASOVIEW 6 PRO meet the established acceptance criteria and performs in a manner equivalent to the predicate device. No new safety or effectiveness issues were raised during the testing program. The results of the verification testing for the VASOSHIELD Pressure Controlling Syringe also demonstrate that the syringe meets established acceptance criteria and performs in a manner equivalent to its predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Maquet Cardiovascular, LLC
% Ms. Artie Kaushik
Associate, Regulatory Affairs
170 Baytech Drive
San Jose, California 95134

AUG 28 2009

Re: K091733

Trade/Device Name: VASOVIEW 6 PRO Endoscopic Vessel Harvesting System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI, GBX
Dated: July 31, 2009
Received: August 4, 2009

Dear Ms. Kaushik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

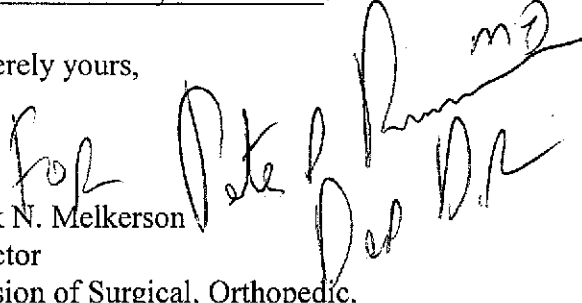
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device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX B: INDICATIONS FOR USE STATEMENT

510(k)
number
(if known)

The 510(k) number has not been issued yet.

Device name

VASOVIEW 6 PRO Endoscopic Vessel Harvesting System

Indications for
Use

The VASOVIEW 6 PRO System is indicated for use in minimally invasive surgery allowing access for vessel harvesting, and is primarily indicated for patients undergoing endoscopic surgery for arterial bypass. It is indicated for cutting tissue and controlling bleeding through coagulation, and for patients requiring blunt dissection of tissue including dissection of blood vessels, dissection of blood vessels of the extremities, dissection of ducts and other structures in the extraperitoneal or subcutaneous extremity and thoracic space. Extremity procedures include tissue dissection/vessel harvesting along the saphenous vein for use in coronary artery bypass grafting and peripheral artery bypass or radial artery for use in coronary artery bypass grafting. Thoracoscopic procedures include exposure and dissection of structures external to the parietal pleura, including nerves, blood vessels and other tissues of the chest wall.

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PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE
IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐


(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

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